California Rice

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RE: PROPOSED AMENDMENT TO SECTIONS 25821(a) AND (c) LEVEL OF EXPOSURE TO CHEMICALS CAUSING REPRODUCTIVE TOXICITY: CALCULATING INTAKE BY THE AVERAGE CONSUMER OF A PRODUCT

Dear Ms. Vela:

On behalf of the state's 2500 rice farmers and 40 markets of rice, the California Rice Commission ("Commission") offers the following comments regarding the proposed amendments to sections 25821(a) and (c) of the California Code of Regulations relative to level of exposure and calculating intake.

The Office of Environmental Health Hazard Assessment ("OEHHA") seeks to add the following language to section 25821.

> For purposes of this section, where a business presents evidence for the "level in question" of a listed chemical in a food product based on the average of multiple samples of that food, the level in question may not be calculated by averaging the concentration of the chemical in food products from different manufacturers or producers, or that were manufactured in different manufacturing facilities from the product at issue.

Use of the term producer

The use of the term 'producer' when referring to averaging concentrations of a chemical in a food is inappropriate, misleading and not applicable when considering level of exposure to a manufactured food product. The term producer should be eliminated or appropriately defined to ensure that raw agricultural products and the growers who produce these products are not included as outlined within the scope of the regulation.

Inclusion of the term producer is confusing. The California Food and Agricultural Code generally defines the term producer to mean any person that is engaged in the business of growing or producing any commodity for commercial use.[1] The Commission specifically defines producer to mean any person who produces, or causes to be produced, rice.[2] There are several other commissions that similarly define and use the term producer.[3] Further, within agriculture the term is uniformly understood to mean the grower of a raw agricultural product be it a grain, fruit, vegetable, animal or dairy. A producer is never construed to be the manufacturer of a consumer product, which appears to be the focus of the proposed regulatory change.

Due to widespread practice of comingling, or mixing, of raw agricultural products between the farm and the final consumer package, production at the grower level should not be included when considering the level of exposure at the manufacturing level. As provided in our previous comments of November 17, 2015 on the pre-regulatory proposal, rice from one farm is mixed with rice from many farms during the drying and storage process. Rice is further mixed at the mill when shipments from several storage facilities are received to process a customer order. These practices are nearly universal within the production and movement of raw agricultural products. It would be impossible to accurately address the level of any Prop 65 chemical within a raw agricultural commodity without some element of averaging a product from different producers.

The Commission recommends the elimination of the term producer from this regulation leaving the point of averaging appropriately at the manufacturer. At a minimum, the term producer must be defined to mean only a manufacturer of a consumer product for the purposes of this regulation. Given that the term "manufacturer" is already included within the regulation, it will be far less confusing if OEHHA simply eliminated this term.

<u>Limitation of averaging to arithmetic mean</u>
The Commission disagrees with the premise that the calculation of exposure should be exclusively by use of the arithmetic mean. This proposal is not supported by the science of data analysis or the regulatory approaches of U.S. EPA or California DPR.

Currently, Title 27 California Code of Regulations (CCR) §25821(c)(2) provides guidance for calculating the Level of Exposure to Chemicals Causing Reproductive Toxicity. In that section, Paragraph (c)(2) states:

> *"For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research*

[1] See Cal. Food & Agr. Code §59510
[2] Cal. Food & Agr. Code § 71032
[3] Cal. Food & Agr. Code §75523

Report, Foods Commonly Eaten by individuals: Amount Per Day and Per Eating Occasion, where such data are available."

OEHHA purports to seek clarification of the correct method for calculating the level of exposure to a listed chemical by specifying that the arithmetic mean must be used for this calculation.

OEHHA, assumes this clarification is necessary because *"The Act and its existing implementing regulations are not sufficiently specific about how the intake or exposure of an average consumer to reproductive toxicants is to be determined. Lack of clarity can lead to incorrect or inconsistent determinations as to whether product-related exposures to these toxicants are exempt…."*[4]

The proposed approach, however, is not scientifically valid and is not the historical position of the State of California. In application, adopting "arithmetic mean" as the mandatory method of calculation will lead to incorrect and inconsistent determinations of product-related exposures to the average consumer. Specifically, the proposal to calculate average exposures using only the arithmetic mean is the *incorrect* method to characterize the average rate of intake for many product exposures where the underlying data do not follow a normal distribution. Further, the use of the arithmetic mean will result in *inconsistent* treatment of data resulting from various distributions through the application of a one-size fits all approach in direct contradiction to the standard, well-established approach to correct and consistent data analysis.

Amendment would lead to incorrect or inconsistent determinations rather than clarify method

A regulatory requirement that arbitrarily uses the arithmetic mean in all exposure calculations with no exceptions will not be supported in many exposure situations where the data (i.e., the intake rate and/or the level in question) are not normally distributed. Yet the proposed amendment does not acknowledge this scenario nor provide an alternative approach that would allow a case by case evaluation of the data to result in a statistically valid estimate of exposure. That is, although the arithmetic mean may be an appropriate estimate of "intake or exposure of an average consumer" in some cases it will not be valid in many others.

Current law provides the requisite flexibility to apply well-established protocols of data analysis to intake and exposure estimates in order to obtain the best estimate of the average exposure.

OEHHA should not designate a data analysis procedure in the regulations that is not supported in all cases by valid scientific methodology nor ensure the most accurate and valid results. The October 5, 2018 proposed amendment leads to the use of an intake of exposure rate that will not provide accurate or valid predictions of an average consumer's exposure in many cases.

[4] Initial Statement of Reasons (ISOR) OEHHA October, 2018, p. 3.

The publicly available consumption data in the National Center for Health Statistics (NCHS) National Health and Nutrition Examination Survey (NHANES)[5] allows the estimate of the distribution of the amounts that are consumed by users of a given food. When that distribution is found to be skewed, *e.g.* to have a few individuals that essentially distort the consumption by most of the individuals (see Figure 1 an example of a skewed distribution and a normal distribution), the arithmetic mean is not a reliable or accurate estimate of the "reasonably anticipated rate of intake or exposure for average users of the consumer product" as is required by the statute. Indeed, the Center for Disease Control (CDC) has provided detailed guidance for the proper use of the NHANES[6] data including an on-line tutorial which addresses frequent questions including the appropriate use of the "geometric" and "arithmetic" means.

For example, the CDC notes that "many continuous variables, like food intakes, are by their nature very skewed."[7] Throughout its guidelines, the CDC highlights the importance of considering the shapes of the distribution of values and applying appropriate statistical methods. It makes no scientific sense for OEHHA to prohibit the use of the geometric mean to estimate the rate of intake or exposure when using NHANES data when the lead agency maintaining the NHANES data specifically endorses its use in the case of food consumption distributions.

The NCHS explicitly provides guidance recommending the use of the geometric mean instead of the arithmetic mean in cases where the distribution of data is skewed:

> "Question 6. When should you use geometric means instead of arithmetic means?
>
> Answer: In instances where the data are highly skewed, geometric means should be used. A geometric mean, unlike the arithmetic mean, minimizes the effect of very high or low values, which could bias the mean if a straight average (arithmetic mean) were calculated."[8]

Throughout the guidelines, the authors reference the importance of carefully considering the shapes of the distribution and applying appropriate statistical methods. It is clear from the

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[5] The U.S. Department of Agriculture's (USDA's) Continuing Survey of Food Intakes by Individuals (CSFII) is the basis of the dietary intake estimates contained in USDA's Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion that is specifically referenced in the Proposition 65 regulations at Title 27 of the California Code of Regulations section 25721(d)(4), as an appropriate basis for use in estimating extent of exposure. Beginning in 2002, the NHANES and CSFII dietary data collection efforts were integrated. The dietary component of NHANES is conducted as a partnership between the USDA and the U.S. Department of Health and Human Services (DHHS). DHHS is responsible for the sample design and data collection, and USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing. NHANES is viewed as an authoritative database containing reliable and robust government data on food consumption and is consistently used for regulatory and food safety purposes by public health agencies.

[6] National Health and Nutrition Examination Survey (NHANES) is the food consumption data that is used for Prop 65 analyses as specified in the statute/regulations.

[7] http://www.cdc.gov/nchs/data/nhanes/nhanes3/nh3gui.pdf

[8] https://www.cdc.gov/nchs/tutorials/NHANES/FAQs.htm.

guidelines that NHANES is a complex, multistage survey and it is not appropriate to use the same methods for every dataset or for every purpose.[9] Finally, these surveys are the same surveys referenced in the OEHHA regulations to estimate the rate of intake of exposure of an average consumer, providing another basis for confusion rather than clarity in analysis.[10]

Regulations require analysis of exposure to average user (population) not individuals.

OEHHA argues that the "average consumer" is best represented by the arithmetic mean "regardless of the shape of the distribution that best describes the sampling data." OEHHA supports its argument by citing two references:

(1) US EPA (1992), Supplemental Guidance to RAGS: Calculating the Concentration Term[11]
(2) California DPR (2003), Memorandum: Why Worker Health and Safety Branch uses Arithmetic Means in Exposure Assessment[12]

US EPA (1992) recommends using the arithmetic mean rather than the geometric mean, however, this recommendation refers to estimating the average of the long-term exposure of an "individual" not for a "population". As stated by EPA (1992): "*Most Agency health criteria are based on the long-term average daily dose, which is simply the sum of all daily does divided by the total number of days in the averaging period.*" The arithmetic mean is in fact the approach currently used to estimate the average consumption for each individual in the population (or per capita) when using data from What We Eat In America (WWEIA), the dietary component of the National Health and Nutrition Examination Surveys (NHANES) or when using frequency of consumption data to estimate long-term intakes. Specifically, WWEIA collects data on food consumption on two non-consecutive days, and, for each individual in the population, the estimate of the long-term consumption of a specific food is obtained as the arithmetic mean of their reported consumption on the two days. Similarly, when using the frequency of consumption data, the long-term average is obtained by using each individual's number of consumption days (say 15 days per month) divided by the reference period (or 30 days) to get the arithmetic average of their long-term consumption.

Similarly, California DPR (2003), argues that the arithmetic mean is the appropriate measure for estimating the long-term occupational exposure of a single individual. It states: "*If daily exposure in µg/day were measured every work day of a work season, the sum of a person's daily measurements would be his total measured seasonal exposure. The same value would be obtained by multiplying the person's arithmetic mean daily exposure by the number of days*

[9] http://www.cdc.gov/nchs/data/ nhanes/nhanes3/nh3gui.pdfd, accessed 10/16/2015.
[10] 27 CCR § 25721(d)(4)
[11] US EPA (1992), Supplemental Guidance to RAGS: Calculating the concentration term. Publication 9285.7-081. Washington DC: Office of Solid Waste and Emergency Response. Available at: https://nepis.epa.gov/Exe/ZyPDF.cgi/9100UGLV.PDF?Dockey=9100UGVL.PDF.
[12] DPR (California Department of Pesticide Regulation, 2003). Memorandum: Why Worker Health and Safety Branch uses Arithmetic Means in Exposure Assessment. Worker Health and Safety Branch, DPR, September 22, 2003.

worked". This is the same approach that is currently being used when estimating the long-term consumption for each individual using the WWEIA data or the frequency of consumption data.

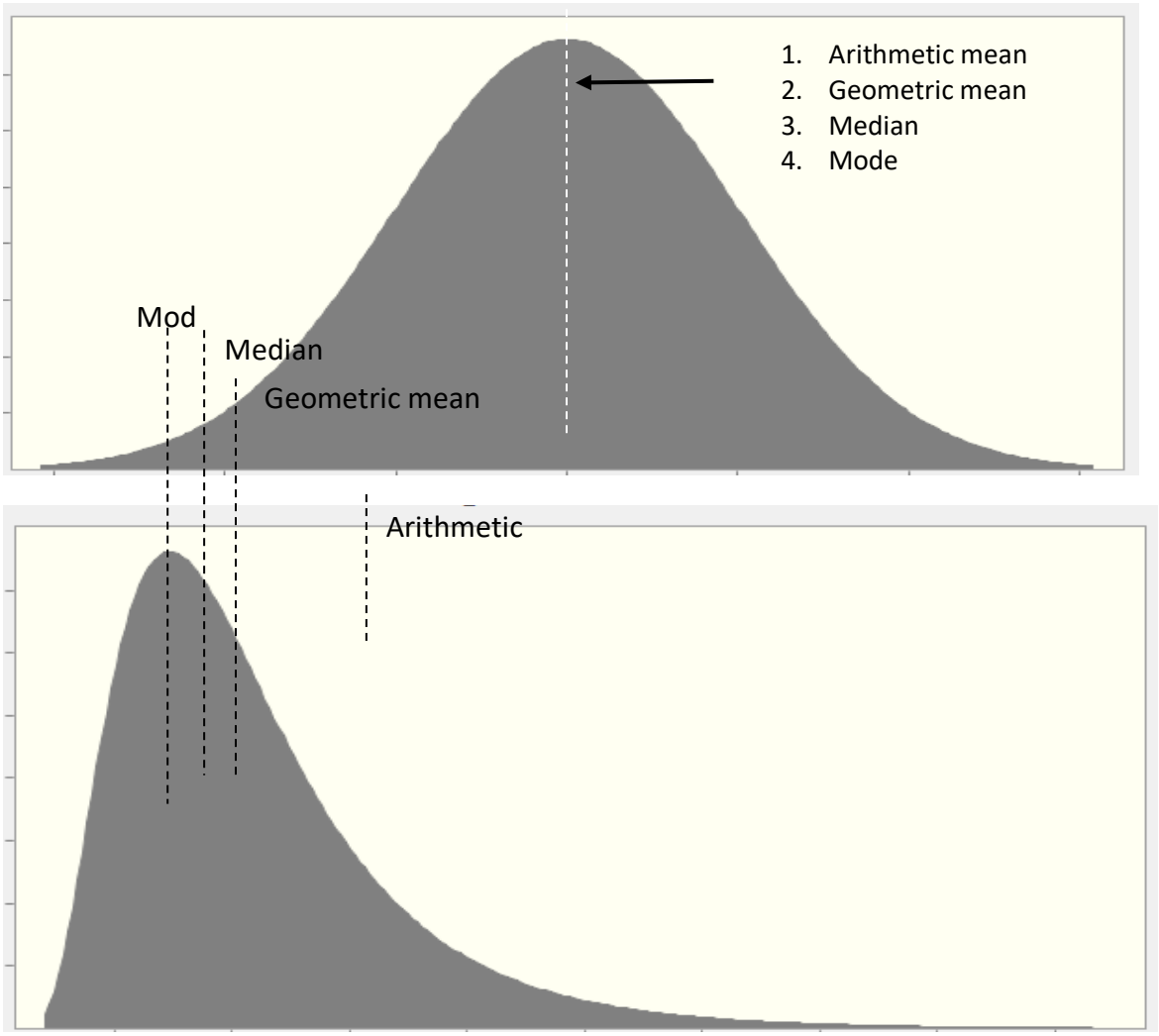
As discussed above, when the distribution of the arithmetic averages for the entire population is symmetric and the arithmetic mean is located where most of the population is, then the arithmetic mean can be used to estimate the consumption of the "average consumer". When that distribution is skewed, however, then the arithmetic mean is typically not located where most of the population is. (See Exhibit "A" included and attached hereto.) In that case, as discussed above, the geometric mean is the appropriate representation of the "average consumer".

In conclusion, the Commission opposes this proposed revision to the regulation and recommends that in every analysis under Proposition 65, careful thought and appropriate scientific and statistical knowledge be applied to analyzing the data set and selecting the methods. Given today's tools for analyzing data and the scientific expertise within OEHHA, there is no justification for selecting a non-scientific and arbitrary metric for use in assessing compliance with Proposition 65.

Sincerely,

Timothy A Johnson
President and CEO
California Rice Commission

EXHIBIT "A"


1. Arithmetic mean
2. Geometric mean
3. Median
4. Mode
Mod
Median
Geometric mean
Arithmetic